OCT - 6 2006

510(k) SUMMARY of Safety and Effectiveness

1. GENERAL INFORMATION

Trade Name	PASS 2 Spinal System
Common Name	Pedicle Screw Spinal System
Classification Name	Orthosis, spinal pedicle fixation
Class	II
Product Code	MNI, MNH
21 CFR section	888.3070
Device panel	Orthopedic
Legally marketed predicate devices	USS (Synthes)= K982987 MOSS MIAMI (Depuy Spine)= K964024 PASSMed (MEDICREA)= K032094
Submitter	MEDICREA® Technologies Z.I. Chef de Baie 17000 La Rochelle, France
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 E-Mail: ortho.medix@sbcglobal.net

2. DEVICE DESCRIPTION

The PASS 2 Spinal System consists of pedicle screws, rods, nuts and clamps. It can be used for single or multiple level fixations. All components are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F136.

3. INTENDED USE

The PASS 2 Spinal System consists of pedicle screws, rods, nuts and clamps members utilized to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a pedicle screw system, the PASS 2 Spinal System is intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

4. PERFORMANCE DATA

Testing performed according to ASTM F1717 indicate that the PASS 2 Spinal System is as mechanically sound as other devices commercially available.

5. SUBSTANTIAL EQUIVALENCE

The PASS 2 Spinal System is similar to the USS (K892987), the MOSS MIAMI (K964024) and PASSMed (K032094) distributed by Synthes, Depuy and Medicrea respectively

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MEDICREA Technologies
% Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

OCT - 6 2006

Re: K062136
Trade/Device Name: PASS2 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Orthosis, spinal pedicle fixation
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: July 24, 2006
Received: July 26, 2006

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: PASS2 Spinal System

Indications for Use:

The PASS 2 Spinal System consists of pedicle screws, rods, nuts and clamps members utilized to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

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Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Mcnamara

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062136